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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office
HFL-35

60 8th Street, N.E.
Atlanta, Georgia 30309

July 31, 1997

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Daniel C. Hauck
Owner
Alphagen Laboratories, Inc.
11525 N. Fulton Industrial Blvd.
Alpharetta, Georgia 30201

WARNING LETTER

Dear Mr. Hauck:

An inspection of your facility and your associated drug repackaging facility [redacted] was conducted between June 30 and July 7, 1997, by Investigator Leah M. Andrews. The inspection revealed numerous significant deviations at both firms from the Current Good Manufacturing Practice for Finished Pharmaceuticals (CGMPs), as set forth in Title 21 of the Code of Federal Regulations (21CFR), Part 211. These deviations cause your repacked drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

Although your firm operates primarily as an own label distributor of drug products, Alphagen had retained responsibility for several critical quality assurance aspects of the repackaging operation. These responsibilities included examination of incoming bulk drugs and labeling, labeling issuance, and reconciliation of the labeling utilized.

Section 510(c) of the Act requires that every firm engaged in the manufacture, preparation, propagation, compounding, or processing of a drug product to register with the Food and Drug Administration (FDA). Manufacturing or processing includes manipulation, sampling, testing, or control procedures applied to the final product or to any part of the process. The quality control responsibilities retained by Alphagen would cause your firm to meet this definition of an establishment required to register. Since your firm did not register with FDA, your drug products would be considered to be misbranded in accordance with Section 502(o) of the Act.

You have failed to implement appropriate controls over incoming bulk drug products to ensure that they will be withheld from use until the products have been sampled, tested, or examined, as appropriate. You could provide no documentation that any of the incoming drug products which were subsequently repacked had been examined prior to their release to [redacted]. You informed Investigator Andrews that the products were never physically examined by anyone at your firm. You have failed to establish any written procedures describing the receipt, identification, storage, handling, sampling, testing, and release of drug products for repackaging.

Similarly you have failed to implement appropriate control over the labeling to be used on your repackaged drug products. You could provide no documentation that any of the labeling had been examined upon receipt or at any point prior to release to [redacted]. You had not established any procedures which addressed the receipt, storage, review, and release of labeling. No attempt was made to maintain an inventory of the labels used on your drug products. No records were available which could be used to reconcile the quantity of labels received, placed into inventory, released to [redacted] utilized on product, or returned to inventory at Alphagen.

You have also failed to maintain an individual inventory record for the drug products repackaged and distributed under the Alphagen label. This record should contain sufficient information to allow determination of any repackaged lot of drug product associated with the use of the incoming bulk lot. This lack of control over the inventory was also noted in the finished products stored in your warehouse.

We are in receipt of your July 17, 1997 response to the inspection. The primary corrective action proposed is the shifting of many of the above quality assurance responsibilities to [redacted]. If this is done, you would no longer be required to register with FDA. However, based on our inspection of [redacted] we have no assurance that they have the appropriate controls in place to assume these responsibilities. We would encourage you to work closely with [redacted] to assure that the procedures implemented are sufficient and would meet your needs.

The above deviations were included on the FDA 483 (Inspectional Observations) which was issued to and discussed with you at the conclusion of the inspection. The violations noted in this letter and in the FDA 483 are symptomatic of serious underlying problems in your firm's quality assurance systems.

The deviations discussed above and included on the FDA 483 should not be construed as an all inclusive list of violations which may be in existence at your firm. It is your responsibility to ensure adherence to each requirement of the Act. You are responsible for investigating and determining the causes of the violations identified by FDA. You should take immediate action to correct these violations. Failure to promptly correct these deviations may result in legal sanctions provided by the law such as product seizure and/or injunction, without further notice to you. Federal agencies are advised of the issuance of all warning letters involving drugs so that they may take this information into account when considering the award of contracts.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed. Your response should include a timetable for transfer of responsibilities to [redacted] and copies of any procedures implemented as a result of this inspection. The response should also include your plans to dispose of the large stocks of drug product with short expiration dates currently stored at your firm. Your response should be addressed to Philip S. Campbell, Compliance Officer, at the address noted in the letterhead.

Sincerely,

for Roger E. Kline

Ballard H. Graham, Director
Atlanta District